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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,657	11/20/2003	Joseph V. Boykin JR.	004629.00024	7388
22907	7590	03/09/2006	EXAMINER	
BANNER & WITCOFF 1001 G STREET N W SUITE 1100 WASHINGTON, DC 20001			LEARY, LOUISE N	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,657

Applicant(s)

BOYKIN, JOSEPH V.

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-17,19-31,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-17,19-31,33 and 34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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1. Claims 1-3, 5-17, 19-31, and 33-34 are pending in this application.

Claims 4, 18 and 32 have been canceled per applicant's request in the amendment filed December 15, 2005.

2. The rejection of claims 1-34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been maintained in-part.

3. The rejection of claims under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McMahon et al (Nature Medicine, Vol. 8 No. 7; pp 711-717, (2002) has been withdrawn in favor of the official office action given below.

GROUND OF REJECTION:

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-17, 19-31, and 33-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the active chemical reagents and/or active kit reagents disclosed in the specification, does not reasonably

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provide enablement for any and all chemical reagents inherently having the desired properties that will be discovered in the future. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The specification discloses a finite number or kind of active chemicals that can be used to perform the instantly claimed methods. As a result, the specification also discloses a finite number or kind of active chemicals that can be included in the instantly claimed kit. However, the invention as claimed encompasses any and all active chemical reagents having the desired properties that will be discovered in the future.

Therefore, the invention as presently claimed is not commensurate in scope with the specification.

5. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is indefinite because the kit claimed does not set forth the kind nor amount of chemical(s) present. Alternatively, the metes and bounds intended by the kit claim cannot be determined.

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-17, 19-31, and 33-34 are rejected under 35 U.S.C. 103(a) as obvious over McMahon et al (Nature Medicine, Vol. 8 No. 7; pp 711-717, (2002) in combination with Dodson et al (Clinical Research, Vol. 11, No. 6, pp 129-135, (November/December 1999).

McMahon et al disclose methods that measure nitric oxide (NO) in blood and provide important data for clinical decision-making. McMahon et al report "[To determine whether the exposure to air in the course of sample handling can affect NO disposition within Hb, triggering the formation of SNO-Hb, we measured levels of SNO-Hb and Hb[FeNO] in human venous blood processed either in room air or in a glove box (O₂ controlled chamber) set to a pO₂ approximating that measured in the venous blood]". See page 712. Regarding the "threshold value" limitations claimed, McMahon et al report evaluating and monitoring patient's blood before, during and after pO₂ treatments. Note pages 711-716. With respect to determining whether a patient will respond favorably to hyperbaric oxygen therapy, McMahon et al report "[The ability to monitor and manipulate blood levels of NO, in conjunction with O₂ and carbon dioxide, may therefore prove useful in the diagnosis and treatment of many human conditions and in the development of new therapies.]" With respect to the limitations describing "nitric oxide-related product" in the specimen, McMahon et al disclose or suggest by-products of NO bioactivity in the blood samples assayed which would inherently include

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nitrate or nitrite. Note pages 711-716. Regarding instant claims 26-27, McMahon et al also address nitric oxide bioavailability. See Figures 1-4) on pages 712-7-15. In addition, regarding the kit described in claim 34, McMahon et al report using reagents for the measurement of Hb-NO in blood samples. See page 716.

With respect to the instant claim limitations “determining whether a patient will respond favorably to hyperbaric oxygen therapy treatment” recited in the instant claims, McMahon et al disclose “[The ability to monitor and manipulate blood levels of NO, in conjunction with O₂ and carbon dioxide, may therefore prove useful in the diagnosis and treatment of many human conditions and in the development of new therapies.]” See the abstract. Further, McMahon et al describe NO production increases, decreases and bioactivity in blood samples. See pages 712-714. Thus, McMahon et al disclose the invention as claimed except for using the phrases “determining whether a patient will respond favorably to hyperbaric oxygen therapy treatment” and “selected from urine or wound fluid”.

However, regarding “determining whether a patient will respond favorably to hyperbaric oxygen therapy treatment” and “selected from urine or wound fluid”, Dodson et al disclose determining NO production in diabetic wound fluid and urine samples to predict favorable treatment with hyperbaric oxygen (HBO). See column 1, page 130 and pages 129-135. Dodson et al “[Our main hypothesis is that treatments that are effective will increase the production of nitric oxide (NO) in the chronic non-healing wound. In addition, increased production is an early event that could serve as a rapid indicator of treatment effect. In other words, effective treatments will cause increased

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HO production, whereas treatments that have little effect will not increase NO.]” See column 1, page 130. Also, Dodson et al disclose “stable end products of NO including nitrate and 3-nitrotyrosine (3-NT) have been used as an indirect measure of NO production.

The correlation between healing and increase NO production has been demonstrated in the non-healing diabetic wound. Non-healing diabetic wound exudates fluid nitrate levels have been shown to be decreased relative to wound exudates from surgical wounds of normal subjects, suggesting that NO production is deficient in diabetic patients.¹⁰ In a recent report, we have shown that when non-healing diabetic foot wounds are treated with topical platelet-derived growth factor (PDGF)*, urine nitrate levels are two-fold lower ($P < 0.01$) for patients whose wounds still fail to heal compared to those whose wounds respond and heal.]”. See column 1 page 130. In view of this disclosure, Dodson et al disclose or suggest the instant limitations “determining whether a patient will respond favorably to hyperbaric oxygen therapy treatment” and “selected from urine or wound fluid”.

Hence, McMahon et al disclose the invention claimed except for addressing the instant limitations “determining whether a patient will respond favorably to hyperbaric oxygen therapy treatment” and “selected from urine or wound fluid” that were provided by Dodson et al.

Therefore, it would have been obvious to one having ordinary skill in this art at the time this invention was made to provide the invention claimed because McMahon et al disclose or suggest the instant invention except for directly disclosing or suggesting

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the instant limitations “determining whether a patient will respond favorably to hyperbaric oxygen therapy treatment” and “selected from urine or wound fluid” that were provided earlier by Dodson et al which renders the invention as claimed obvious.

7. No claim is allowed.

8. The Ranta et al (Obstetrics & Gynecology, Vol. 93, No. 3, (March 1999) disclose assessing NO production by simultaneously measuring “plasma levels and renal clearance of nitrite and nitrate in 20 women...” and has been cited to further show the state of this art.

The Haung et al (Neuroscience Letters, Vol. 293, pp 159-162, (2000); and Boykin, Jr. references (US 6,436,366 B2; 6,312,663 B1 and 6,344,181 B2) have been cited to further show the state of this art.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is 571-272-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LOUISE N. LEARY
PRIMARY EXAMINER

February 24, 2006